

DOCKET NO.: DIBIS-0002US.P3 (Counsel Docket No. 10450)**PATENT****REMARKS****I. Claim Cancellations**

Claims 23-43 were pending in the present application. In order to further the Applicants' business interests and not in acquiescence to the arguments of the Office Action, claims 28-29 and 35-43 have been cancelled. Applicants reserve the right to pursue the cancelled claims in one or more continuing applications.

II. New Claims

New claims 44-55 have been added. Claims 44-49 depend from claim 23 and claims 50-55 depend from claim 30.

Support for new claims 44 and 50, wherein the virus is a respiratory pathogen, is found, for example on page 30, lines 18-19.

Support for new claims 45 and 51, wherein the virus is a hepatitis C virus is found, for example, on page 36, lines 15-18.

Support for new claims 46 and 52, wherein the virus is an immunodeficiency virus is found, for example, on page 29, lines 1-6 and in Figure 15 (Drawing Sheet 26).

Support for new claims 47 and 53, wherein the virus is a member of a viral family selected from the group consisting of *Filoviridae*, *Flaviviridae*, *Arenaviridae*, *Bunyaviridae*, *Adenoviridae*, *Picornaviridae*, *Togaviridae*, and *Coronaviridae*, is found, for example, on page 21, lines 25, 30 and on page 36, lines 19-28.

Support for new claims 48 and 54, wherein the housekeeping gene encodes a polymerase, a virion component, a helicase, a protease, a methyltransferase, or an accessory protein, is found, for example, on page 35, lines 26-32.

Support for new claims 49 and 55, wherein the polymerase is RNA-dependent RNA polymerase, DNA-dependent DNA polymerase or DNA-dependent RNA polymerase is found, for example, on page 35, lines 26-29 and page 63, lines 1-3.

All of the newly added claims are fully supported in the specification and do not comprise new matter.

III. Claim Amendments

Claims 23, 27, and 30 have been amended.

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Claim 23 has been amended to recite that the molecular mass of the amplification product is measured by mass spectrometry. Support for this amendment is found, for example, on pages 20-25 and in the original claims. Claim 23 has also been amended to recite that the comparing step compares the molecular mass of the amplification product with four or more molecular masses of amplification products of four or more members of the viral family. Support for this amendment is found, for example, on page 55, lines 1-6.

Claims 23 and 30 have both been amended to recite that the amplification products of members of the viral family are produced by the same (said) pair of primers. Support for this amendment is found, for example, in Table 2 on page 40. Also in claims 23 and 30, the term "bioagent identifying amplicon" has been deleted and the term "amplification product" has been added.

Claim 27 has been amended to recite "electrospray ionization time-of-flight" mass spectrometry. Support for this amendment is found, for example on page 21, lines 17-20 and 21-23.

Upon entry of the amendment, claims 23-27, 30-34 and 44-53 will be pending.

IV. Remarks

1. The Office Action interprets the meaning of the term "molecular mass" broadly to encompass any mode of determination of molecular mass. In order to further Applicants' business interests, and not in acquiescence to the arguments of the Office Action, the Applicants have amended claim 23 to recite "determining the molecular mass of said amplification product by mass spectrometry."

"In the Office Action of March 17, 2006, the Examiner asserts:

"The term "database" is also repeatedly used. The term is not defined in the specification. The ordinary meaning of "database" is a "collection of information." Any collection of information, such as a set of reference nucleic acid positions, would satisfy this claim limitation."

The Office Action is in error. Neither the originally filed claims, nor the claims filed in the Preliminary Amendment dated December 2, 2005, nor the present claims contain the term "database." Hence, the term "database" is not a "claim limitation" as alleged.

The Office Action argues that, since no length for the variable region is required, a

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single SNP between two members would represent a region of 0% homology and would meet the limitations of the claims. Applicants disagree with this argument. However, to further Applicants' business interests, and not in acquiescence to the arguments of the Office Action, the Applicants have deleted the claim elements relating to percent sequence identity of conserved and variable regions.

V. Response to Claim Rejections**Novelty**

3. Claims 23, 25, 30 and 32 have been rejected under 35 U.S.C 102(b) as being anticipated by Figueiredo, 1998.

4. Claims 23, 25, 26, 30, 32, 33, 37, 39 and 40 have been rejected under 35 U.S.C 102(b) as being anticipated by Fujioka, 1995.

5. Claims 23, 25-27, 30, 32-34, 37 and 39-41 have been rejected under 35 U.S.C 102(b) as being anticipated by Jurinke, 1996.

Obviousness

8. Claims 24, 31 and 38 have been rejected under 35 U.S.C 103(a) as being unpatentable over Fujioka, 1996 in view of Campbell, 1996.

9. Claims 24, 31 and 38 have been rejected under 35 U.S.C 103(a) as being unpatentable over Jurinke, 1996 in view of Campbell, 1996.

10. Claims 28, 29, 35, 36, 42 and 43 have been rejected under 35 U.S.C 103(a) as being unpatentable over Fujioka, 1996 in view of Kilpatrick, 1996.

11. Claims 28, 29, 35, 36, 42 and 43 have been rejected under 35 U.S.C 103(a) as being unpatentable over Jurinke, 1996 in view of Kilpatrick, 1996.

Obviousness-Type Double Patenting

12. Claims 23-43 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59, 60, 62, 63, 66, 69-76 and 79-94 of copending application No. 10/156,608 in view of Jurinke, 1996.

13. Claims 23-43 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending application No. 10/156,608.

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A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference. MPEP 2131, citing *Verdegaal Bros v. Union Oil Co. of California*, 814, F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

3. The Claimed Invention is not Anticipated by Figueiredo, 1998.

Claims 23, 25, 30 and 32 have been rejected under 35 U.S.C 102(b) as being anticipated by Figueiredo, 1998. Applicants assert that in light of the current amendment of claims 23 and 30, these claims are not anticipated by Figueiredo, 1998, because this reference does not teach all of the elements of the rejected claims. With regard to claim 23, for example, Figueiredo does not disclose measurement of molecular mass by mass spectrometry. With regard to claim 30, for example, Figueiredo does not disclose measurement of base composition.

For at least these reasons, Applicants submit that amended claims 23 and 30, and all claims dependent thereon, are not anticipated by Figueiredo, 1998.

4. The Claimed Invention is Not Anticipated by Fujioka, 1995

Claims 23, 25, 26, 30, 32, 33, 37, 39 and 40 have been rejected under 35 U.S.C 102(b) as being anticipated by Fujioka, 1995. Claims 37, 39 and 40 have been cancelled, thus rendering these rejections moot. Applicants assert that in light of the current amendment of claims 23 and 30, these claims and all pending claims dependent thereon are not anticipated by Fujioka, 1995, because this reference does not teach all of the elements of the rejected claims. With regard to claim 23, for example, Fujioka does not disclose measurement of molecular mass by mass spectrometry. With regard to claim 30, for example, Figueiredo does not teach measurement of base composition.

For the reasons argued above, Applicants submit that amended claims 23 and 30 and all claims dependent thereon are not anticipated by Fujioka, 1995.

5. The Claimed Invention is Not Anticipated by Jurinke, 1996

Claims 23, 25-27, 30, 32-34, 37 and 39-41 have been rejected under 35 U.S.C 102(b)

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as being anticipated by Jurinke, 1996. Claims 37 and 39-41 have been cancelled, thus rendering these rejections moot. Applicants assert that in light of the current amendment of claims 23 and 30, these claims and all pending claims dependent thereon are not anticipated by Jurinke, 1996, because this reference does not teach all of the elements of the rejected claims.

With regard to claims 23, for example, Jurinke does not teach the step of comparing the molecular mass of the amplification product with four or more known molecular masses of known amplification products of four or more members of the viral family. Instead, the measured molecular mass (20754 Da) of the human hepatitis B virus is compared with only a single molecular mass (20735 Da) of the human hepatitis B virus (see page 70, column 1).

With regard to claim 30, for example, Jurinke does not teach measurement of base composition.

For the reasons argued above, Applicants submit that amended claims 23 and 30, and all claims dependent thereon are not anticipated by Jurinke, 1996.

VII. The Claimed Invention is Not Obvious

Prima facie obviousness requires 1) an evidence-based suggestion or motivation to combine or modify the reference teachings; 2) the prior art must provide reasonable expectation of success should the suggested combination or modification take place; and 3) the prior art must teach or suggest all of the claim limitations. A showing of obviousness fails if any one of these elements is not met.

8. Fujioka, 1995 in view of Campbell, 1996

Claims 24, 31 and 38 have been rejected under 35 U.S.C 103(a) as being unpatentable over Fujioka, 1996 in view of Campbell, 1996. Claim 38 has been cancelled, thus rendering this rejection moot. With regard to claim 24, which is dependent on amended claim 23, Applicants assert that the Examiner's combination of Fujioka and Campbell does not teach or suggest each of the claim elements. For example, the teaching of measurement of molecular mass by mass spectrometry is absent in both references. With regard to claim 31, which is dependent on amended claim 30, Applicants assert that the Examiner's combination of Fujioka and Campbell does not teach or suggest each of the claim elements. For example, the teaching of measurement of base composition is absent in both references.

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Claims 24, 31 and 38 have been rejected under 35 U.S.C 103(a) as being unpatentable over Jurinke, 1996 in view of Campbell, 1996. Claim 38 has been cancelled, thus rendering this rejection moot. With regard to claim 24, which is dependent on amended claim 23, Applicants assert that the Examiner's combination of Jurinke and Campbell does not teach or suggest each of the claim elements. For example, the Examiner's combination of references does not teach a step of comparing the molecular mass of the amplification product with four or more known molecular masses of known amplification products of four or more members of the viral family. With regard to claim 31, which is dependent on amended claim 30, Applicants argue that the Examiner's combination of Jurinke and Campbell does not teach or suggest each of the claim elements because disclosure of measurement of base composition is absent in both references.

10. Claims 28, 29, 35, 36, 42 and 43 have been rejected under 35 U.S.C 103(a) as being unpatentable over Fujioka, 1996 in view of Kilpatrick, 1996. Claims 28, 29, 35, 36, 42 and 43 have been cancelled, thus rendering this rejection moot.

11. Claims 28, 29, 35, 36, 42 and 43 have been rejected under 35 U.S.C 103(a) as being unpatentable over Jurinke, 1996 in view of Kilpatrick, 1996. Claims 28, 29, 35, 36, 42 and 43 have been cancelled, thus rendering this rejection moot.

VIII. Obviousness-Type Double-Patenting

As requested in the Office Action dated 03/17/2006, point 15, while making no admission with regard to obviousness-type double patenting, Applicants herein identify the co-pending applications of the same patent family which the Examiner may wish to review with regard to obviousness-type double patenting: 10/156,608, 10/660,997, 10/660,122, 10/660,998, 11/233,630, 11/331,978, and 11/331,987.

12. Co-pending Application Serial No. 10/156,608 in view of Jurinke, 1996

Claims 23-43 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59, 60, 62, 63, 66, 69-

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76 and 79-94 of co-pending Application Serial No. 10/156,608 in view of Jurinke, 1996. A terminal disclaimer with regard to 10/156,608 is filed herewith.

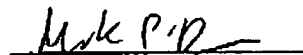
13. Co-pending Application Serial No. 10/660,997

Claims 23-43 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of co-pending Application Serial No. 10/660,997. A terminal disclaimer with regard to 10/660,997 is filed herewith.

Conclusions

In view of the foregoing, Applicants submit that the claims of the instant application are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there should be any questions with regard to the claimed invention.

Respectfully submitted,



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